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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

OTSUKA PHARMACEUTICAL CO., LTD., )  
Plaintiff, ) **DOCUMENT ELECTRONICALLY FILED**  
v. )  
INTAS PHARMACEUTICALS LIMITED, ) C.A. No. 14-cv-06158-JBS-KMW  
ACCORD HEALTHCARE, INC., ACCORD )  
HEALTHCARE LIMITED, ASTRON )  
RESEARCH LIMITED and HETERO LABS )  
LIMITED, )  
Defendants. )

**DEFENDANT'S ANSWER TO PLAINTIFF'S COMPLAINT FOR PATENT  
INFRINGEMENT, COUNTERCLAIMS, AND DEMAND FOR TRIAL BY JURY**

Defendant Hetero Labs Limited ("Hetero"), by and through its undersigned counsel, hereby responds to the Complaint for Patent Infringement by Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Plaintiff") as follows:

### **THE PARTIES**

1. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and, therefore, denies those allegations.

2. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and, therefore, denies those allegations.

3. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 3 of Complaint and, therefore, denies those allegations.

4. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Complaint and, therefore, denies those allegations.

5. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 5 of the Complaint and, therefore, denies those allegations.

6. Admitted.

### **NATURE OF THE ACTION**

7. Hetero admits that Plaintiff's Complaint purports to be an action for infringement of U.S. Patent No. 8,759,350 arising under the United States patent laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281, related to Accord Healthcare, Inc.'s filing of an Abbreviated New Drug Application (ANDA) under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sell, offer to sell and import generic pharmaceutical products prior to the expiration of the asserted patents. Hetero denies that Plaintiff has any basis for its claims against Hetero.

**JURISDICTION AND VENUE**

8. Paragraph 8 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it does not contest subject-matter jurisdiction in this case.

9. Paragraph 9 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 9 of the Complaint, and therefore, denies those allegations.

10. Paragraph 10 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 10 of the Complaint and, therefore, denies those allegations.

11. Paragraph 11 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 11 of the Complaint and, therefore, denies those allegations.

12. Paragraph 12 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 12 of the Complaint and, therefore, denies those allegations.

13. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 13 of the Complaint and, therefore, denies those allegations.

14. Paragraph 14 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it does not contest personal jurisdiction in this judicial district for the limited purpose of this action. Hetero further states that Hetero's website speaks for itself. Hetero further admits that it manufactures, imports, markets and sells generic drugs throughout the United States.

15. Paragraph 15 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states that it does not contest that venue is proper in this district for purposes of Plaintiff's claims against Hetero in this action.

#### **FIRST COUNT FOR PATENT INFRINGEMENT**

16. Hetero admits that a document purporting to be a copy of U.S. Patent No. 8,759,350 ("'350 Patent") entitled "Carbostyryl Derivatives and Serotonin Reuptake Inhibitors For Treatment of Mood Disorders," and stating on its face that it issued on June 24, 2014, is attached as Exhibit A to the Complaint.

17. Hetero admits that Otsuka Pharmaceutical Co., Ltd. is listed on the face of Exhibit A as the purported assignee of the '350 Patent.

18. Hetero admits the electronic version of the *Orange Book: Approved Products with Therapeutic Equivalence Evaluations* (the "Orange Book") published by the FDA lists the patent expiration date for the '350 patent as March 2, 2027. Hetero denies all other allegations in paragraph 18 of the Complaint.

19. Paragraph 19 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero denies the allegations in paragraph 19 of the Complaint.

20. Hetero admits that Otsuka is listed as the applicant for New Drug Application

(“NDA”) No. 21-436 for aripiprazole tablets on FDA’s website with an approval date of November 15, 2002. Hetero denies all other allegations in paragraph 20 of the Complaint.

21. Hetero admits that the '350 Patent is currently listed in the electronic version of the *Orange Book* in connection with NDA No. 21-436. Hetero denies all other allegations in paragraph 21 of the Complaint.

22. Admitted

23. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Complaint and, therefore, denies those allegations.

24. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 24 of the Complaint and, therefore, denies those allegations.

25. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 25 of the Complaint and, therefore, denies those allegations.

26. Hetero is without information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 26 of the Complaint and, therefore, denies those allegations.

27. Hetero denies that it has infringed at least one claim of the '350 Patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-6251 seeking approval to manufacture, use, import, offer to sell and sell Accord Healthcare, Inc.’s generic products before the expiration date of the '350 Patent. Hetero is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 27 of the Complaint and, therefore, denies those allegations.

28. Hetero denies that it has cooperated with, participated in, assisted, induced, or benefitted from, any infringement of the '350 Patent. Hetero is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 28

of the Complaint and, therefore, denies those allegations.

29. Hetero denies that it will actively aid, abet, encourage and induce Accord Healthcare, Inc. and others in the manufacture, use, import, offer for sale and sale of Accord Healthcare, Inc.'s generic products before the expiration date of the '350 patent. Hetero is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 29 of the Complaint and, therefore, denies those allegations.

**ANSWER TO PRAYER FOR RELIEF**

Defendant denies that Plaintiff is entitled to the judgment and relief Plaintiff requests in the Complaint.

**AFFIRMATIVE DEFENSES**

**First Affirmative Defense**

Plaintiff's § 271(a)-(c) infringement claim fails to state a claim under Rule 12(b)(6). Plaintiff bases its § 271(a)-(c) claim against Hetero on alleged possible future acts of infringement by Accord Healthcare, Inc. if the FDA proves Accord Healthcare, Inc.'s ANDA in the same form as currently filed. Such highly speculative acts of alleged future infringement by a party other than Hetero cannot support a claim of direct and indirect infringement under § 271(a)-(c). Plaintiff has not alleged any past or present infringement in the Complaint to support its § 271(a)-(c) claims of infringement.

**Second Affirmative Defense**

Hetero does not infringe and has not infringed any valid and enforceable claim '350 Patent, and will neither induce nor contribute to the infringement of any valid and/or enforceable claim of the '350 Patent, either literally or under the doctrine of equivalents.

Third Affirmative Defense

Each and every claim of the '350 Patent is invalid because they fail to satisfy one or more conditions for patentability stated in Title 35 of the United States Code, including, *inter alia*, §§ 101, 102, 103 and 112.

Fourth Affirmative Defense

Plaintiff's claims for relief are barred, in whole or in part, by the doctrine of prosecution history estoppel.

Fifth Affirmative Defense

Plaintiff's claims for relief are barred, in whole or in part, by one or more of the equitable doctrines of laches, waiver, estoppel and/or unclean hands.

Sixth Affirmative Defense

Plaintiff's claims for injunctive relief are barred because Plaintiff has an adequate remedy at law, has not been irreparably harmed, the balance of hardships is not in its favor and the public interest is not served by granting injunctive relief.

Seventh Affirmative Defense

Plaintiff's claims for damages are limited and/or barred under 35 U.S.C. §§ 286 and 287.

Eighth Affirmative Defense

Hetero reserves the right to assert additional defenses that may become known to it through discovery, including, but not limited to, inequitable conduct.

### **COUNTERCLAIMS**

Hetero, for its Counterclaims against Otsuka, alleges as follows:

1. Hetero Labs Limited is an Indian corporation having a principal place of business at 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad, 500 018 A.P., India.
2. Upon information and belief, Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

### **JURISDICTION AND VENUE**

3. These Counterclaims arise under the Federal Declaratory Judgments Act, 28 U.S.C. §§ 2201, 2202, under the United States patent laws, 35 U.S.C. § 1 *et seq.*, and under 21 U.S.C. § 355(j)(5)(C).
4. This Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331, 1118(a), 2201, and 2202, and 21 U.S.C. § 355(j)(5)(C)(i)(ii).

5. Personal jurisdiction over Counterclaim-Defendant exists because Counterclaim-Defendant has submitted to the personal jurisdiction of this Court.

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c), 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(ii).

### **BACKGROUND**

7. On information and belief, the United States Patent and Trademark Office issued U.S. Patent No. 8,759,350 (“the ‘350 Patent”) on June 24, 2014, listing Otsuka as the assignee.
8. Counterclaim-Defendant Otsuka filed the Complaint in this district on October 2, 2014, claiming infringement of the ‘350 Patent and alleging that Hetero has infringed on the ‘350 Patent.

9. Hetero denies infringement of the '350 patent and alleges that the '350 patent is invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Patent Laws, including 35 U.S.C. §§ 101, *et seq.*

10. Therefore, there is an actual and justiciable case or controversy between Hetero and Otsuka regarding the alleged infringement and validity of the '350 patent.

**COUNT I**

**(Declaratory Judgment of Non-Infringement of the '350 Patent)**

11. Hetero re-alleges and incorporates each of the preceding paragraphs 1-10 as if fully stated herein.

12. Hetero has not infringed, does not infringe, will not infringe, and will not contribute to or induce the infringement of any valid and/or enforceable claim of the '350 Patent, either literally or under the doctrine of equivalents.

13. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Hetero requests a declaration from the Court that Hetero has not and will not infringe the claims of the '350 Patent.

**COUNT II**

**(Declaratory Judgment of Invalidity of the '350 Patent)**

14. Hetero re-alleges and incorporates each of the preceding paragraphs 1-11 as if fully stated herein.

15. Each claim of the '350 Patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

16. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Hetero requests a declaration from the Court that each of the claims of the '350 Patent is invalid.

**PRAYER FOR RELIEF**

**WHEREFORE**, Hetero respectfully requests that this Court enter a Judgment and Order in its favor and against Counterclaim-Defendant as follows:

- A. Dismissing Counterclaim-Defendant's First Amended Complaint and rendering judgment in favor of Hetero;
- B. Declaring that Hetero does not and will not infringe any valid and/or enforceable claim of the '350 Patent;
- C. Declaring that the claims of the '350 Patent are invalid;
- D. Declaring that this is an exceptional case under 35 U.S.C. § 285 and/or other applicable laws and awarding Hetero its attorneys' fees, costs and expenses in this action; and
- E. Awarding to Hetero such further relief as this Court may deem necessary, just, and proper.

**DEMAND FOR JURY TRIAL**

Hetero demands a trial by jury.

Dated: October 31, 2014

Respectfully submitted,

*s/ David Leit*

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**CERTIFICATION OF SERVICE**

I, Lawrence Bluestone, of full age, do hereby certify that on October 31, 2014, I caused to be electronically filed a true and correct copy of Defendant Hetero Labs Limited's Answer to Plaintiff's Complaint for Patent Infringement, Counterclaims, and Demand for Trial by Jury, and that such filing constitutes service on all counsel of record by virtue of counsel's registration with the Court to receive electronic filings.

Dated: October 31, 2014

s/ Lawrence Bluestone  
Lawrence Bluestone